REMARKS

This Amendment is being filed in response to the Office Action mailed on September 15, 2006.

Claims 1-48 and 64 of the present application have been amended to recite that the drug is "metoprolol or a pharmaceutically acceptable salt thereof". Claims 49-63 have been amended to recite that the drug is metoprolol succinate. The claims have also been amended to require a controlled release coating surrounding the drug layer, wherein said coating comprises (i) a water insoluble film forming polymer; (ii) a channeling agent; and (iii) optionally an emulsifier. Additional amendments and cancellation of claims have been made in light of the above amendments. No new matter has been added.

On pages 2-3 of the Office Action the Examiner rejected claims 1-6, 8, 9, 12, 13, 17-20, 27, 28, 30-32, 49-54, 56, 57, 61, 64 and 65 under 35 U.S.C. §102(e) as being anticipated by United States Patent No. 7,022,342 (hereinafter "Chen et al.").

On pages 3-5 of the Office Action the Examiner rejected claims 1-6, 8, 9, 12, 13, 17-23, 27-54, 56, 57 and 60-65 under 35 U.S.C. § 103(a) as being unpatentable over Chen et al. in view of WO 99/61005 (hereinafter "Sriwongjanya et al.").

On pages 5-6 of the Office Action the Examiner rejected claims 7, 10, 11, 14-16, 24-26, 49, 55, 58 and 59 under 35 U.S.C. § 103(a) as being unpatentable over Chen et al. in view of United States Patent No. 6,569,463 (hereinafter "Patel et al.").

Reconsideration of the above rejections is respectfully requested.

As a preliminary matter, Applicants do not believe that the rejection of the pending claims under 35 U.S.C. §103(a) is appropriate. These rejections rely upon the Chen reference as the primary reference. The Chen reference is only prior art under 35 U.S.C. § 102(e). Because the Chen reference is owned by the same entity as the present application, (namely Andrx) the use of the Chen reference is improper under 35 U.S.C. §103(c). If the Examiner maintains the rejection under 35 U.S.C. § 103, in view of the following arguments, appropriate declarations to establish the ownership will be submitted.

In order to appreciate the patentability of the present claims a brief discussion of the prior art metoprolol formulations is required. United States Patent Nos. 4,957,745

(the '745 patent) and 4,927,640 (the '640 patent) teach controlled release dosage forms that employ insoluble cores for delivering metoprolol or a pharmaceutically acceptable salt thereof. The '745 and '640 patents only teach the use of insoluble cores because the combination of water soluble materials with metoprolol caused an increase in the osmotic pressure that led to the bursting of dosage forms and premature dumping of the drug (see present application page 1, last paragraph).

Additionally, the use of the insoluble cores necessitated the use of organic solvents such as methylene chloride to coat the cores. This leads to increased production costs due to manufacturing, regulatory and environmental difficulties.

Applicants have surprisingly discovered a metoprolol dosage form that overcomes these problems and employs metoprolol coated water soluble/water swellable cores. The present invention solves the problems associated with metoprolol formulations through the novel use of a combination of excipients, water soluble/water swellable cores, and controlled release coatings.

The Chen et al. reference is not directed towards controlled release dosage forms that deliver metoprolol or a pharmaceutically acceptable salt thereof, and therefore was never intended to solve the problems associated with the delivery of metoprolol using water soluble excipients. While Applicants agree that many of the excipients recited in the claims of the present application are listed in the Chen et al. reference (including metoprolol), Applicants submit that there is no teaching in the Chen et al. reference that would allow one to produce a controlled release metoprolol pellet with a water soluble/water swellable core without undue experimentation.

Sriwongjanya et al. does not cure the deficiencies that exist in the Chen et al. reference and therefore does not render the claims of the present application obvious. Specifically, Sriwongjanya et al. (like Chen et al.) is not directed towards controlled release dosage forms comprising metoprolol and water soluble/water swellable cores.

Sriwongjanya et al. discloses oral controlled release dosage formulations containing an analgesic, and more specifically, controlled release dosage formulations containing tramadol. Further, the cores of the dosage forms disclosed in the Sriwongjanya et al. reference are prepared using wet granulation techniques that produce homogenous cores containing the pharmaceutical agent. In sharp contrast the present

invention employs coating the metoprolol (and additional excipients) onto the inert water soluble/water swellable cores. These are wholly different procedures.

Patel et al. also does not cure the deficiencies that exist in the Chen et al. reference and therefore does not render the claims of the present application obvious. Specifically, Patel et al. is not directed towards controlled release dosage forms comprising metoprolol. While Applicants agree that the specification of Patel et al. does recite that "metoprolol" is a drug that may be employed in the Patel et al. formulations, metoprolol is only one of hundreds of drugs listed in the specification. Further, there are no specific examples directed towards metoprolol. Also, the use of sugar as a substrate is merely recited in a list of possible substrates (Patel et al. is practically a dictionary of possible excipients that can be used in pharmaceutical preparations). The critical factor is that there is absolutely no direction in Patel et al. to make a controlled release dosage form comprising metoprolol employing a water soluble/water swellable core.

Based upon the above remarks and amendments Applicants respectfully submit that Claims 1, 3-49 and 51-64 are allowable and that the present application is in proper form for allowance.

An early and favorable action is earnestly solicited.

Respectfully submitted,

Nicholas P. Chiara
Registration No: 52,737

MAILING ADDRESS

Hedman & Costigan, P.C.
1185 Avenue of the Americas
New York, NY 10036
(212) 302-8989